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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,429	01/04/2002	Jeffrey H. Burbank	266/153	7194
21890	7590	11/17/2004	EXAMINER	
PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299			FRANK, RODNEY T	
			ART UNIT	PAPER NUMBER
			2856	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/037,429	<b>Applicant(s)</b> BURBANK, JEFFREY H.	
	<b>Examiner</b> Rodney T. Frank	<b>Art Unit</b> 2856	<i>AC</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17, 18, 20, 60, 61, 70-74 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 60, 61, 70-72, 74 and 81-83 is/are rejected.
- 7) ☒ Claim(s) 20 and 73 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is an apparatus claim, yet the end of the claim state "... comprising the steps of:", which is usually claim language for a method claim.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventor's Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 17, 60, 61, 70, 71, 74, 81, and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Mahony et al. (U.S. Patent Number 6,585,675; hereinafter referred to as O'Mahony). O'Mahony discloses a method and apparatus for controlling blood withdrawal and

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infusion flow rate with the use of a pressure controller. The pressure controller uses pressure targets based upon occlusion limits that are calculated as a function of flow. The controller has the ability to switch from controlling withdrawal pressure to controlling infusion pressure based upon the detection of an occlusion. The controller distinguishes between partial and total occlusions of the withdrawal vein providing blood access. Depending on the nature of occlusion, the controller limits or temporarily reverses blood flow and, thus, prevents withdrawal vessel collapse or reverses blood flow to quickly infuse blood into the vessel without participation from operator (Please see the abstract).

With respect to claim 17, O'Mahony discloses and shows in figures 1 and 2, a device for detecting leaks in a blood circuit comprising a first leak detector (118) that detects leaks by sensing any presence of blood outside said blood circuit, said first leak detector being located to detect leaks from a first portion of said blood circuit located remote from a patient; said outside being a non-wetted environment of said-blood circuit, a second leak detector (117) that detects leaks by sensing air infiltration into lines under negative pressure; said second leak detector being configured to detect leaks in lines connecting said patient to said first portion; a mechanism that insures that at least part of said lines are under negative pressure at least part of the time during a treatment such that a detectable air infiltration indicates a presence of a leak in said lines; an alarm device that outputs an alarm signal responsively to a detection of a leak by said first or second leak detector. The device being kept under negative pressure is described, for example, in column 11 lines 27 through 34.

With respect to claim 60, O'Mahony discloses and shows in figures 1 and 2, a device for detecting a leak from a blood circuit an extracorporeal blood treatment machine, comprising the steps of: respective detectors located to detect leaks of blood from respective portions of a blood

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circuit (117 and 118) ; at least two of said respective detectors including sensors configured to detect different physical effects correlated with one or more blood leaks; said respective portions including parts that are non-overlapping; wherein said different physical effects include the infiltration of air into a blood circuit and the presence of blood outside said blood circuit; said-outside being a non-wetted-e. environment of said blood circuit: an output device connected to receive signals from said respective detectors and to output a signal responsively thereto and an alarm connected to generate an output responsively to said signal; wherein said output device and detectors are configured such that said signal indicates a leak if either of said respective different physical effects indicates a leak; wherein at least one of said detectors includes an air sensor (117) or bubble sensor and a mechanism adapted to periodically generate a negative pressure in said blood circuit such that air infiltrates said blood circuit through any openings therein.

With respect to claim 61, it is disclosed that the device can reverse blood flow in the abstract.

With respect to claim 70, O'Mahony discloses and shows in figures 1 and 2, a device for detecting leaks in an extracorporeal blood circuit, comprising: a liquid detector positioned to detect blood or liquid outside a first portion said outside being a non-wetted environment of said-blood-circuit (118): an air detector positioned to detect air inside a second portion of the blood of a blood circuit (117) that is remote from the first portion; a positive displacement mechanism configured to periodically generate a negative pressure in said blood circuit such that air is caused to be infiltrated in portions that are otherwise not under negative pressure; and an alarm configured to signify the occurrence of a leak in response to either or both of said liquid detector and said air detector.

With respect to claim 71, O'Mahony discloses the use of a reversing pump in column 18 lines 12 through 24.

With respect to claim 74, O'Mahony discloses and shows in figures 1 and 2, a method of detecting leaks in a blood treatment machine, comprising the steps of: during a treatment operation, detecting liquid outside a blood circuit, at least a first portion of which is under non-negative pressure during a treatment operation; said outside being a non-wetted environment of said blood circuit; creating a temporary negative pressure at least two times during said treatment operation in at least a second portion of said blood circuit effective to cause air to infiltrate said second portion; detecting said air caused to infiltrate by said step of creating; at least one of halting a pumping of blood in either or both of said first and second blood circuit portions or generating an alarm signal responsively to a result of either or both of said steps of detecting. This method is described in claims 1-11 of the O'Mahony reference.

With respect to claim 81, O'Mahony discloses and shows in figures 1 and 2, a device for detecting leaks in a blood treatment circuit comprising: a first leak detector (118) that detects leaks by sensing liquid in an otherwise dry outside environment of said blood treatment circuit, said first leak detector being located to detect leaks from at least a first portion of said blood treatment circuit; a second leak detector (117) that detects leaks by sensing air or bubble infiltration into lines of said blood treatment circuit under negative pressure; said second leak detector being configured to detect leaks at least in said lines of said blood treatment circuit that connect said patient to said first portion; a positive displacement mechanism that insures that at least part of said lines are under negative pressure at least part of the time during a treatment such that a detectable air or bubble infiltration indicates a presence of a leak in said lines; an alarm device that monitors said

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first and second leak detectors during a treatment and generates a response signal responsively to a detection of a leak by said first or second leak detector.

With respect to claim 83, a pump with reversible flow is disclosed.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18, 72 and 82 rejected under 35 U.S.C. 103(a) as being unpatentable over O'Mahony. The examiner admits that the specific limitations of these claims are not disclosed (i.e. a second liquid fluid detector, the detector position within the device housing or an audio alarm), the examiner feels that these limitations are mere design choices that are well within the preview of one of ordinary skill in the art as they do not provide any advantage nor improvement over the prior art nor does their implementation provide any unexpected result in view of the prior art.

***Allowable Subject Matter***

6. Claims 20 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*


7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The examiner has cited various references that are deemed as relevant to the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney T. Frank whose telephone number is (571) 272-2193. The examiner can normally be reached on M-F 9am -5:30p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTF  
November 14, 2004

  
**HEZRON WILLIAMS**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 2800**